DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



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MEMORANDUM

TO: Medicare Employer Group Prescription Drug Plan Applicants

FROM: Mark Hamelburg, Director, Employer Policy and Operations Group

RE: Timeline and Process for Issuing Determinations on Employer/Union Group

Applications

DATE: May 19, 2005

The Medicare Modernization Act (MMA) provides employers and unions with a number of options for providing prescription drug coverage to their Medicare-eligible retirees. Under Part D of the MMA, those options include making special arrangements with Medicare Advantage plans (MA-PDs) and Cost Plans to purchase customized benefits, including drug benefits, for their retirees; purchasing benefits from sponsors of prescription drug-only plans (PDPs); and contracting with CMS to become Part D plan sponsors themselves (direct contract arrangements). Each of these approaches involve a retiree group application process which incorporates the use of CMS waivers authorized under Section 1857(i) and 1860D-22(b) of the Social Security Act. This memorandum describes CMS' timeframe for review and approval of these retiree group applications (see attached timelines).

Another option available to most employers and unions is to receive a tax-free retiree drug subsidy that generally pays 28 percent of a retiree's drug costs (as defined by the regulation) between \$250 and \$5,000 in 2006. That option offers highly flexible rules that permit employers and unions to continue providing drug coverage to their Medicare-eligible retirees at a lower cost while retaining their current plan designs. Information about the retiree drug subsidy is located at http://www.cms.hhs.gov/medicarereform/pdbma/employer.asp. Additional information relating to the retiree drug subsidy application process will be provided in future announcements.

Key Part D Dates and Processes

As we conduct employer/union group application reviews, we will be notifying applicants of incomplete and/or deficient sections of the application along with target dates to resubmit the information. As noted on the attached timelines, any such resubmitted information **must be** completed and submitted to CMS no later than close of business June 15, 2005. However, applicants that did not meet certain pharmacy access requirements by the application deadline are given the opportunity to provide follow-up pharmacy access analysis by August 1, 2005. Additional guidance on submitting these pharmacy access analyses will be provided in early June 2005.

For applicants who meet all sections of the application, CMS will issue conditional approval letters no later than June 29, 2005. Similarly, letters of intent to deny will be issued to all other applicants by June 29, 2005, except for applicants providing follow-up pharmacy access analyses on August 1, 2005. These entities will receive conditional approval letters as long as they have no other deficiencies in their applications other than the pharmacy access requirements.

All applicants that receive a letter of intent to deny may attempt to cure the deficiencies identified by CMS within 10 days. If the additional documentation proves satisfactory, these applicants will receive conditional approval letters. Such applicants may also request a formal denial or withdraw their application.

By mid-September, CMS plans to send contracts to applicants that have met all application requirements and had their bids accepted. For PDP, MA-PD and Cost Plan sponsors with non-retiree group market contracts, appropriate employer/union provisions will be added to those contracts. In late August, 2005, applicants that fail to meet the follow-up pharmacy access requirements or have their bids rejected will receive a letter of intent to deny.

In making this announcement, we wish to clearly state the implications of this application review process. Allowing applicants additional time to complete and satisfy the pharmacy access requirements could impact an applicant's ability to appeal application denials in time to participate in contract year 2006. Regulations at 42 CFR Part 423, Subpart N, allow applicants to seek three levels of administrative review of application denials. These regulations further provide that entities seeking to appeal a denial must have a favorable redetermination on that appeal by July 15 in order for the contract to be effective on January 1 of the following year. Accordingly, employer group applicants that take advantage of the extended timeframe and that do not demonstrate pharmacy access compliance until the August 1, 2005 follow-up submission could be unable to participate in the 2006 contract year if CMS determines their applications are insufficient. This will be the case even if the applicant prevails under the appeals procedures of Subpart N of the regulation. A favorable redetermination on appeal received after July 15, 2005, would render the applicant qualified to contract as a Part D sponsor for the 2007 contract year (although the applicant would still need to submit an approved bid for 2007).

Applicants that receive a conditional letter of approval should work with CMS to meet the follow-up pharmacy access requirements and provide the submission due August 1, 2005. Some may wish to request a formal denial to enable them to pursue a formal appeal under Subpart N in the hopes of gaining a favorable redetermination prior to the July 15, 2005 cut-off. We will issue formal denials in lieu of conditional approvals if requested. Please note that employers and unions that receive formal denials will still have enough time to apply for the retiree drug subsidy, assuming they are otherwise qualified.

CMS appreciates the cooperative spirit of employers, unions, Part D plan sponsors, and their advisors in this extraordinary year. We remain committed to working with applicants to ensure that retirees have quality drug benefit choices. Please contact Julian Nadolny at 410-786-2274, or Marye Isaacs at 410-786-3276 if you have questions about this timeline and process for employer group applications.

Attachments:

- (1) 2006 Medicare Part D Employer Group Application Timeline: Employer/Union Direct Contract PDPs
- (2) 2006 Medicare Part D Employer Group Application Timeline: PDPs, MA-PDs, Cost Plans

Attachment 1

April 25, 2005	Receipt Of Employer/Union Direct Contract PDP Applications
April 28-June 1, 2005	Review of Employer/Union Direct Contract PDP Applications
No later than June 3, 2005	CMS Provides Feedback to Employer/Union Direct Contract PDP Applicants With Incomplete or Deficient Application Sections
June 6, 2005	All Employer Group Formularies Due
June 15, 2005	Last Day For Applicants To Send Identified Incomplete And/or Deficient Sections Of Application Information To CMS
June 25-29, 2005	CMS sends "Status of Application" letters to applicants. An applicant can receive either a letter of intent to deny or a conditional approval. Conditional approvals will be granted only to applicants whose only remaining open issue is receipt of the follow-up pharmacy access analyses by August 1, 2005. The conditional approval letters will indicate steps that remain to be completed by the employer/union. All other deficiencies (other than pharmacy access) will result in a letter of intent to deny indicating that the applicant has 10 days to cure the deficiencies, and steps to seeking appeals rights.
July 1, 2005	Employer/Union Direct Contract PDP Bids Due
July 15, 2005	Last Date To Receive A Favorable Redetermination Under The Appeals Process In Order To Be Eligible For 2006 Contract Year
August 1, 2005	Follow Up Pharmacy Access (LTC/HI/ITU) Analyses Due
August 26, 2005	Deadline for CMS review of pharmacy access. CMS begins to issue letters of intent to deny for insufficient evidence of pharmacy access. Applicants may withdraw their application.
September 1, 2005	CMS Begins To Sign Contracts For Successful Employer/Union Direct Contract PDP Applicants Who Also Have Approved Bids
September 14, 2005	Last Date for Signing Contracts Date By Which All Contract Approvals are Due to HPMS

Attachment 2

2006 Medicare Part D Employer Group Application Timeline: PDPs, MA-PDs and Cost Plans

April 25, 2005	Receipt of PDP, MA-PD, Cost Plan Employer/Union Group Applications
April 28-June 1, 2005	Review of Employer/Union Group PDP, MA-PD, Cost Plan Applications
No Later Than June 3, 2005	CMS Provides Feedback to Employer Group PDP, MA-PD and Cost Plan Applicants With Incomplete or Deficient Application Sections
June 6, 2005	All Employer/Union Group Formularies Due
June 6, 2005	Employer/Union Group Bids Due For Regional MA-PDs
June 15, 2005	Last Day For Applicants To Send Identified Incomplete And/or Deficient Sections Of Application Information To CMS
June 25-29, 2005	CMS sends "Status of Application" letters to applicants. An applicant can receive either a letter of intent to deny or a conditional approval. Conditional approvals will be granted only to applicants whose only remaining open issue is receipt of the follow-up pharmacy access analyses by August 1, 2005. The conditional approval letters will indicate steps that remain to be completed by the employer group applicant. All other deficiencies will result in a letter of intent to deny indicating that the applicant has 10 days to cure the deficiencies, and steps to seeking appeals rights.
July 1, 2005	Employer/Union Groups Bids Due For PDPs, Local MA-PDs, Cost Plans
July 15, 2005	Last Date To Receive A Favorable Re-Determination Under The Appeals Process In Order To Be Eligible To Offer Employer/Union Group Coverage For 2006 Contract Year
August 1, 2005	Follow Up Pharmacy Access (LTC/HI/ITU) Analyses Due For Non-Retiree Group Market (see CMS Memorandum from Bob Donnelly Re: Timeline and Process For Issuing Determinations On PDP Applications, dated May 9, 2005)
September 1, 2005	CMS Begins To Sign Non-Retiree Group Market PDP, MA-PD, and Cost Plan Contracts With Addenda For Customized

Employer/Union Group Applicants Who Also Have Approved Applications and Bids

September 14, 2005

Last Date for Signing Contracts
Date By Which All Contract Approvals Are Due to HPMS